REMARKS

Applicant has noted the rejections set forth in the Office Action mailed February 2, 2003. For the reasons set forth beginning on page 11 of this paper, Applicant respectfully traverses the rejections. Applicant states that the current claim listing starting on page 3 of the Reply and Request for Reconsideration should be placed in the binding copy. Pursuant to 37 C.F.R § 1.121(f), no new matter has been added to the application in the amended specification or claims, but is intended to *only* more accurately reflect the invention and better aid in the understanding and comprehension of the claimed device.

Claims 1-11, 13-18 and 20 are not present as the result of an earlier restriction requirement.

ARGUMENT

The examiner has rejected claims 12 and 19 under 35 U.S.C. § 112, second paragraph, for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Applicant traverses this rejection and respectfully points out that the use of Applicant's method/process to improve the selection of the best immunogenic peptide from a protein of known sequence and production of antisera against it for use on clinical diagnosis is regarded as part of the invention. Specifically, on page 5, second paragraph: "A still further object is to provide monoclonal and polyclonal antibodies highly specific for the peptide epitopes of the present invention which may be utilized in diagnostic testing procedures..." Again, on page 17, last paragraph, "The Ho-Hi-Ho epitopes of the present invention can be used in diagnostic tests, such as immunoassays, to detect viruses, microbes and malignant cells. ... Certain preferred immunoassays are various type of enzyme linked immunoabsorbent assays, radioimmunoassay, immunofluorescence and surface plasmon resonance. Immunohistochemical detection using tissue sections is also particularly useful. However, it should be appreciated that detection methods are not limited to such techniques, and Western blotting, dot blotting, FACS analyses and the like may be used." It is clear by the above statements that Applicant regards the use of his method/process to create a diagnostic test to detect abnormal states such as caused by infection (viral or microbial) and cancer.

The examiner has also rejected claims 12 and 19 under 35 U.S.C.§ 112, first paragraph, as not being enabled and restricted to PSA and Gelonin. Once more, Applicant traverses this rejection and respectfully points out that a person of ordinary skill in the art would be able, by following the steps described and using the software provided (or another preferred software), to obtain immunogenic peptides from any globular protein of known sequence. The addition of the information regarding the globular PSA and Gelonin was to illustrate the workings of the inventions to help understanding and enabling, not to restrict the invention.

The examiner suggests that detection of binding of antisera to a polypeptide is not indicative of diagnosis since all proteins have this potential and not all proteins are linked to disease. Applicant agrees that mere binding is not sufficient, but argues that concentration of the protein is key for diagnosis (see specification page 2, first paragraph "Many antigens have been studied as possible serum markers for different types of cancer because the serum concentrations of the specific antigen may be an indication of the cancer stage in an untreated person."). Therefore, Applicant has amended the claim to include this valid criticism.

Applicant respectfully disagrees with the NGF example provided by the examiner. It is true that presence of a protein, without a context, does not provide much information, but even presence or absence of a protein within a clinical context could be indicative. For example, increase in blood sugar and absence (or diminishing) in the presence of administered insulin are indicative of

diabetes. It is also true that NGF is a growth hormone associated with normal function in neuronal tissue, but is also equally true that it has a role in regulation of B cell activation and that lower plasma levels of NGF have been found in HIV-1 infected individuals as well as natural anti-NGF antibodies. Also, recent studies indicate a correlation between increased levels of NGF expression and a positive prognosis in children that suffer from severe brain injury, suggesting that levels of NGF could be diagnostic of outcome after brain injury. Also, downregulation of NGF and its receptors has been found in gastric cancer as well as the increased presence of NGF in patients' sputa with pulmonary fibrosis. This suggests upregulation of lung sensory neurons and paths for treatment. Finally, detecting levels of NGF could also help to diagnose the progress of a therapy such as intake of NGF for neuropathies developed during HIV-1 infections.

Applicant's invention is a general diagnostic tool in which individuals of other arts, such as clinicians, will provide the context. Applicant doesn't intend to claim knowledge and discovery that other researchers provide to the field of diagnosis. Applicant's only claim is a tool that will facilitate the diagnosis of abnormal states due to infection, disease or injury. Applicant has attempted to restrict scope, by concentrating only on the proteins discussed in the specification (pages 16-17), and points out all of the above mentioned proteins have normal functions in the bodies, but abnormal expression could be indicative of a disease or injury state. It is known in the art that abnormal expression could include upregulation, downregulation or expression in a tissue which usually

doesn't express the protein and that this information in that context could be a useful and powerful diagnostic tool.

Applicant respectfully contends that this application is therefore in a condition of allowance.

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Respectfully submitted,

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